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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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ART UNIT	PAPER NUMBER
1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/660,122	ECKER ET AL.	
	Examiner	Art Unit	
	ANGELA BERTAGNA	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-33 and 50-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-33 and 50-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/28/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on October 28, 2008 has been entered.

Claims 30-33 and 50-62 are currently pending.

Information Disclosure Statement

2. Applicant's submission of an Information Disclosure Statement on October 28, 2008 is acknowledged. A signed copy is enclosed.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 30, 53, and 60 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14-17 of U.S. Patent No. 7,312,036 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 14-17 of the '036 patent recite a species of the methods recited generically in the instant claims 30, 53, and 60, and therefore, the claims of the '036 patent anticipate the methods of the instant claims 30, 53, and 60.

5. Claims 31 and 57 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14-17 of U.S. Patent No. US 7,312,036 B2 in view of Campbell et al. (Journal of Virological Methods (1996) 57: 175-179; cited previously).

The methods recited in the instant claims 30, 53, and 60 are an obvious variant of the methods recited in claims 14-17 of the '036 patent, as discussed above.

The claims of the '036 patent do not teach performing the method using multiple primer pairs as required by the instant claim 31. The claims of the '036 patent also do not specify that the amplification step is a PCR amplification step as required by the instant claim 57.

Campbell teaches the use of multiple primers in order to detect every variant (see page 178, column 1). Campbell also teaches PCR amplification (see pages 176-177).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to modify the method of the '036 patent to use multiple primer pairs since Campbell stated, "By using both sets of primers it is highly unlikely that any variant will go undetected (see page 178, column 1)." Thus, an ordinary artisan, concerned with the problem of missing variants with a mutation in the conserved region of a filovirus, could resolve this concern by repeating the assay with additional primer sets as taught by Campbell, who teaches that the use of additional primer sets will result in improved detection of all variants. An ordinary artisan also would have been motivated to use any form of amplification known to be useful for amplifying viral nucleic acids, such as the PCR amplification method taught by Campbell, recognizing its suitability for the intended purpose. As noted in MPEP 2144.07, selection of a known process based on its suitability for the intended purpose is *prima facie* obvious in the absence of secondary considerations. Thus, the methods of the instant claims 31 and 57 are an obvious variant of the methods recited in claims 14-17 of the '036 patent in view of Campbell.

6. Claims 32, 50-52, 58, 61, and 62 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14-17 of U.S. Patent No. 7,312,036 B2 in view of Koster et al. (WO 98/20166; cited previously).

As discussed above the instant claims 30, 53, and 60 are an obvious variant of claims 14-17 of the '036 patent.

The claims of the '036 patent do not teach applying the method to the detection of a biological warfare agent, a respiratory pathogen, hepatitis C virus, or an immunodeficiency virus, as required by claims 32 and 50-52. The claims of the '036 patent also do not teach that the

primers flank a region about 60-100 nucleotides in length, as required by claim 58. Finally, the claims of the '036 patent do not teach incorporating a molecular mass-modifying tag or a specific nucleotide analog into the amplification product to limit the number of possible base compositions having the mass of the amplification product as required by claims 61 and 62.

Koster teaches methods for analyzing amplification products using mass spectroscopy. Koster also teaches comparison of base compositions with both modified and unmodified products (see page 66, for example, as well as page 105, Table II and pages 69-70). At page 105, Table II, Koster provides the base composition of three different PCR products determined by MALDI-TOF. Further, Koster specifically discusses using base composition to analyze mutations as discussed on page 70, where Koster notes, "MS can also be used to determined full or partial sequences of larger DNAs; this can be used to detect, locate, and identify new mutations in a given gene region." In particular, Koster expressly teaches the use of MALDI-TOF for diagnosis of bacterial or viral infections (see pages 73-79). Koster exemplifies this analysis in Example 5.

Regarding claims 32 and 50-52, Koster teaches analysis of respiratory pathogens such as rhinovirus (see page 74, line 1) as well as influenza virus (see page 74, line 8), which is also a biological warfare agent. Koster also teaches analysis of an immunodeficiency virus (HIV) and HCV, which is a member of the flaviviridae family (see page 73, line 21 and page 74, line 21).

Regarding claim 58, Koster teaches that the amplified products are 67 bp in length (page 87), and therefore, teaches primers that flank a region between 60 and 100 nucleotides in length.

Regarding claim 61, Koster teaches incorporating nucleotide analogs, such as uridine, into the primers (page 40).

Regarding claim 62, Koster teaches incorporating mass tags into the amplification products to limit the number of possible base compositions (see page 66, for example, as well as page 105, Table II and pages 69-70).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to apply the teachings of Koster to the methods recited in the claims of the '036 patent. Since Koster taught that base composition analysis of amplification products was useful for identifying bacterial and viral infections (pages 73-79), an ordinary artisan would have been motivated to expand the method to include analysis of other viral nucleic acids, such as the clinically relevant viral nucleic acid targets identified by Koster (*e.g.* HCV, HIV, *etc*), in order to increase the number of useful applications of the method. An ordinary artisan also would have been motivated to apply the teachings of Koster regarding the size of the amplification products and the use of nucleotide analogs and/or mass modifying tags to the methods recited in the '036 patent recognizing their applicability to the recited methods. Thus, the methods recited in the instant claims 32, 50-52, 58, 61, and 62 are an obvious variant of the methods recited in claims 14-17 of the '036 patent in view of Koster.

7. Claim 33, 54-56, and 59 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14-17 of U.S. Patent No. 7,312,036 B2 in view of Vanderhallen et al. (Journal of Clinical Microbiology (1998) 36(12): 3463-3467; cited previously).

As discussed above the instant claims 30, 53, and 60 are an obvious variant of claims 14-17 of the '036 patent.

The ‘036 patent does not teach that the method amplifies a polymerase gene as required by claims 54-56. The '306 patent does not teach that the method identifies the virus at the species or subspecies level, as required by claims 33 and 59.

Vanderhallen teaches analysis of a polymerase gene for typing EMCV (abstract).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to apply the method recited in the claims of the ‘036 patent to type the clinically relevant EMCV by amplifying a polymerase gene, since Vanderhallen stated, "The PCR technique has increased the sensitivity of detection of viral nucleic acids in clinical specimens (see page 3465, column 2)." An ordinary artisan, interested in improving sensitivity of EMCV detection, would have been motivated to combine the PCR method of Vanderhallen with the mass spectrometric analysis recited in the claims of the '739 patent, in order to identify specific subtypes of viruses that are of clinical significance and permit epidemiological tracking of these viruses. Thus, the methods of the instant claims 33, 54-56, and 59 are an obvious variant of the methods recited in claims 14-17 of the '036 patent in view of Vanderhallen.

8. Claims 30-33 and 50-62 are directed to an invention not patentably distinct from claims 14-17 of commonly assigned US Patent No. 7,312,036. Specifically, as discussed above, the methods recited in the instant claims 30-33 and 50-62 are either anticipated by or are an obvious variant of the methods recited in claims 14-17 of the '036 patent.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned US Patent No. 7,312,036 B2, discussed above, would form the basis for a

rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

9. Claims 30-32 and 50-58 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23-29 of copending Application No. 11/869,449. Although the conflicting claims are not identical, they are not patentably distinct from each other, because claims 23-29 of the '449 application recite a species of the methods generically claimed in the instant claims 30, 31, and 54-56. Therefore, the methods recited in claims 23-29 of the '449 application anticipate the methods recited in the instant claims 30, 31, and 54-56.

Regarding claims 32 and 50-53, it would have been *prima facie* obvious for an ordinary practitioner of the methods recited in claims 23-29 of the '449 application to apply the method to any clinically relevant bioagent (*e.g.* the bioagents recited in the instant claims 32 and 50-53).

An ordinary artisan would have been motivated to do so in order to increase the number of useful applications of the method.

Regarding the instant claim 57, the claims of the '449 application do not specify that the amplification is conducted by PCR. However, it would have been *prima facie* obvious for the ordinary artisan to select any known amplification method (*e.g.* PCR) for use in the method recited in the claims of the '449 application, recognizing its suitability for the intended purpose. As noted in MPEP 2144.07, it is *prima facie* obvious to select a known material or method based on its suitability for the intended purpose.

Finally, regarding the instant claim 58, it would have been *prima facie* obvious for the ordinary practitioner of the methods recited in the claims of the '449 application to perform routine experimentation to determine the optimal size (*e.g.* 60-100 nucleotides) of the amplification products produced in the method. As noted in MPEP 2144.05, performing routine experimentation to optimize known results-effective variables, such as amplification product size, is *prima facie* obvious in the absence of secondary considerations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 30, 32, 50-53, 56-58, and 60 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 6, 8, and 10 of copending Application No. 11/331,987. Although the conflicting claims are not identical, they are not patentably distinct from each other, because claims 1-3 of the '987 application recite a species of the method generically claimed in the instant claim 30. Therefore, the methods

recited in claims 1-3 of the '987 application anticipate the method recited in the instant claim 30. The limitations of the instant claims 56, 58, and 60 are recited in claims 6, 8, and 10 of the '987 application.

Regarding claims 32 and 50-53, it would have been *prima facie* obvious for an ordinary practitioner of the methods recited in claims 1-3, 6, 8, and 10 of the '987 application to apply the method to any clinically relevant bioagent (*e.g.* the bioagents recited in the instant claims 32 and 50-53). An ordinary artisan would have been motivated to do so in order to increase the number of useful applications of the method.

Regarding the instant claim 57, the claims of the '987 application do not specify that the amplification is conducted by PCR. However, it would have been *prima facie* obvious for the ordinary artisan to select any known amplification method (*e.g.* PCR) for use in the method recited in the claims of the '987 application, recognizing its suitability for the intended purpose. As noted in MPEP 2144.07, it is *prima facie* obvious to select a known material or method based on its suitability for the intended purpose.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 30, 32, 50-53, 56-58, and 60 are directed to an invention not patentably distinct from claims 1-3, 6, 8, and 10 of commonly assigned US Application No. 11/331,987. Specifically, as discussed above, the methods recited in the instant claims 30, 32, 50-53, 56-58, and 60 are either anticipated by or are an obvious variant of the methods recited in claims 1-3, 6, 8, and 10 of the '987 application.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned US Application Serial No. 11/331,987, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

12. Claims 30-33 and 50-59 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 88, 89, 92-94, 98, 112-120, 122, 123, 125, 130, 131, 133, 140-148, 150-154, 156, 171-179, 181-183, and 200-206 of copending Application No. 10/728,486. Although the conflicting claims are not identical, they are not patentably distinct from each other, because claims 88, 89, 92-94, 98, 112-120, 122, 123, 125, 130, 131, 133, 140-148, 150-154, 156, 171-179, 181-183, and 200-206 of the '486 application recite a species of the methods generically claimed in the instant claims 30, 31, 33,

50, 53-56, and 59. Therefore, the methods recited in the claims of the '486 application anticipate the methods recited in the instant claims 30, 31, 33, 50, 53-56, and 59.

Regarding the instant claims 32, 51, and 52, it would have been *prima facie* obvious for an ordinary practitioner of the methods recited in the claims of the '486 application to apply the method to any clinically relevant bioagent (*e.g.* the bioagents recited in the instant claims 32, 51, and 52). An ordinary artisan would have been motivated to do so in order to increase the number of useful applications of the method.

Regarding the instant claim 57, the claims of the '486 application do not specify that the amplification is conducted by PCR. However, it would have been *prima facie* obvious for the ordinary artisan to select any known amplification method (*e.g.* PCR) for use in the method recited in the claims of the '486 application, recognizing its suitability for the intended purpose. As noted in MPEP 2144.07, it is *prima facie* obvious to select a known material or method based on its suitability for the intended purpose.

Finally, regarding the instant claim 58, it would have been *prima facie* obvious for the ordinary practitioner of the methods recited in the claims of the '486 application to perform routine experimentation to determine the optimal size (*e.g.* 60-100 nucleotides) of the amplification products produced in the method. As noted in MPEP 2144.05, performing routine experimentation to optimize known results-effective variables, such as amplification product size, is *prima facie* obvious in the absence of secondary considerations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 30-33 and 50-59 are directed to an invention not patentably distinct from claims 88, 89, 92-94, 98, 112-120, 122, 123, 125, 130, 131, 133, 140-148, 150-154, 156, 171-179, 181-183, and 200-206 of commonly assigned US Application No. 10/728,486. Specifically, as discussed above, the methods recited in the instant claims 30-33 and 50-59 are either anticipated by or are an obvious variant of the methods recited in claims 88, 89, 92-94, 98, 112-120, 122, 123, 125, 130, 131, 133, 140-148, 150-154, 156, 171-179, 181-183, and 200-206 of the '486 application.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned US Application Serial No. 10/728,486, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

14. Claims 30-33, 50-53, and 57-62 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23, 27, 28, 33, 36-44, 53, 55-68, 71-74, and 80-94 of copending Application No. 11/929,910. Although the conflicting claims are not identical, they are not patentably distinct from each other, because claims 23, 27, 28, 33, 36-44, 53, 55-68, 71-74, and 80-94 of the '910 application recite a species of the methods generically claimed in the instant claims 30-33, 53, and 57-62. Therefore, the methods recited in the claims of the '910 application anticipate the methods recited in the instant claims 30-33, 53, and 57-62.

Regarding the instant claims 50-52, it would have been *prima facie* obvious for an ordinary practitioner of the methods recited in the claims of the '910 application to apply the method to any clinically relevant bioagent (*e.g.* the bioagents recited in the instant claims 50-52). An ordinary artisan would have been motivated to do so in order to increase the number of useful applications of the method.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 30-33, 50-53, and 57-62 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 29, 30, 34, 35, 40, 43-50, 51, 60, 62-75, 78-81, 87-99, and 101 of copending Application No. 11/929,930. Although the conflicting claims are not identical, they are not patentably distinct from each other, because claims 29, 30, 34, 35, 40, 43-50, 51, 60, 62-75, 78-81, 87-99, and 101 of the '930 application recite a species of the methods generically claimed in the instant claims 30-33, 53, and 57-62.

Therefore, the methods recited in the claims of the '930 application anticipate the methods recited in the instant claims 30-33, 53, and 57-62.

Regarding the instant claims 50-52, it would have been *prima facie* obvious for an ordinary practitioner of the methods recited in the claims of the '930 application to apply the method to any clinically relevant bioagent (*e.g.* the bioagents recited in the instant claims 50-52). An ordinary artisan would have been motivated to do so in order to increase the number of useful applications of the method.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 30-33, 50-53, and 57-62 are directed to an invention not patentably distinct from claims 29, 30, 34, 35, 40, 43-50, 51, 60, 62-75, 78-81, 87-99, and 101 of commonly assigned US Application No. 11/929,930. Specifically, as discussed above, the methods recited in the instant claims 30-33, 50-53, and 57-62 are either anticipated by or are an obvious variant of the methods recited in claims 29, 30, 34, 35, 40, 43-50, 51, 60, 62-75, 78-81, 87-99, and 101 of the '930 application.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned US Application Serial No. 11/929,930, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the

examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

17. Claims 30-33, 50-53, and 57-62 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21, 22, 28-32, 35-50, 53, 54, 57, 60-67, 76-84, and 87-90 of copending Application No. 11/930,108. Although the conflicting claims are not identical, they are not patentably distinct from each other, because claims 21, 22, 28-32, 35-50, 53, 54, 57, 60-67, 76-84, and 87-90 of the '108 application recite a species of the methods generically claimed in the instant claims 30-33, 53, and 57-62. Therefore, the methods recited in the claims of the '108 application anticipate the methods recited in the instant claims 30-33, 53, and 57-62.

Regarding the instant claims 50-52, it would have been *prima facie* obvious for an ordinary practitioner of the methods recited in the claims of the '108 application to apply the method to any clinically relevant bioagent (*e.g.* the bioagents recited in the instant claims 50-52). An ordinary artisan would have been motivated to do so in order to increase the number of useful applications of the method.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. Claims 30-33, 50-53, and 57-62 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22, 23, 28, 29, 34, 37-45, 54, 56-69, and 72-75, and 78-89 of copending Application No. 11/930,017. Although the conflicting claims are not identical, they are not patentably distinct from each other, because claims 22, 23, 28, 29, 34, 37-45, 54, 56-69, and 72-75, and 78-89 of the '017 application recite a species of the methods generically claimed in the instant claims 30-33, 53, and 57-62. Therefore, the methods recited in the claims of the '017 application anticipate the methods recited in the instant claims 30-33, 53, and 57-62.

Regarding the instant claims 50-52, it would have been *prima facie* obvious for an ordinary practitioner of the methods recited in the claims of the '017 application to apply the method to any clinically relevant bioagent (*e.g.* the bioagents recited in the instant claims 50-52). An ordinary artisan would have been motivated to do so in order to increase the number of useful applications of the method.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. Claims 30-33, 50-53, and 57-62 are directed to an invention not patentably distinct from claims 22, 23, 28, 29, 34, 37-45, 54, 56-69, and 72-75, and 78-89 of commonly assigned US Application No. 11/930,017. Specifically, as discussed above, the methods recited in the instant

claims 30-33, 50-53, and 57-62 are either anticipated by or are an obvious variant of the methods recited in claims 22, 23, 28, 29, 34, 37-45, 54, 56-69, and 72-75, and 78-89 of the '017 application.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned US Application Serial No. 11/930,017, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

20. Claims 30-33, 50-53, and 57-62 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 50, 51, 56, 57, 62, 65-73, 82, 84-97, 100-103, and 109-123 of copending Application No. 11/930,002. Although the conflicting claims are not identical, they are not patentably distinct from each other, because claims 50, 51, 56, 57, 62, 65-73, 82, 84-97, 100-103, and 109-123 of the ‘002 application recite a

species of the methods generically claimed in the instant claims 30-33, 53, and 57-62. Therefore, the methods recited in the claims of the '002 application anticipate the methods recited in the instant claims 30-33, 53, and 57-62.

Regarding the instant claims 50-52, it would have been *prima facie* obvious for an ordinary practitioner of the methods recited in the claims of the '002 application to apply the method to any clinically relevant bioagent (*e.g.* the bioagents recited in the instant claims 50-52). An ordinary artisan would have been motivated to do so in order to increase the number of useful applications of the method.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

21. Claims 30-33, 50-53, and 57-62 are directed to an invention not patentably distinct from claims 50, 51, 56, 57, 62, 65-73, 82, 84-97, 100-103, and 109-123 of commonly assigned US Application No. 11/930,002. Specifically, as discussed above, the methods recited in the instant claims 30-33, 50-53, and 57-62 are either anticipated by or are an obvious variant of the methods recited in claims 50, 51, 56, 57, 62, 65-73, 82, 84-97, 100-103, and 109-123 of the '002 application.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned US Application Serial No. 11/930,002, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not

commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

22. Claims 30-33, 50-53, and 57-62 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 35, 36, 41, 42, 47, 50-58, 67, 69-82, 85-88, 91-102, 106, and 107 of copending Application No. 11/929,707. Although the conflicting claims are not identical, they are not patentably distinct from each other, because claims 35, 36, 41, 42, 47, 50-58, 67, 69-82, 85-88, 91-102, 106, and 107 of the '707 application recite a species of the methods generically claimed in the instant claims 30-33, 53, and 57-62. Therefore, the methods recited in the claims of the '707 application anticipate the methods recited in the instant claims 30-33, 53, and 57-62.

Regarding the instant claims 50-52, it would have been *prima facie* obvious for an ordinary practitioner of the methods recited in the claims of the '707 application to apply the method to any clinically relevant bioagent (*e.g.* the bioagents recited in the instant claims 50-52). An ordinary artisan would have been motivated to do so in order to increase the number of useful applications of the method.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

23. Claims 30-33, 50-53, and 57-62 are directed to an invention not patentably distinct from claims 35, 36, 41, 42, 47, 50-58, 67, 69-82, 85-88, 91-102, 106, and 107 of commonly assigned US Application No. 11/929,707. Specifically, as discussed above, the methods recited in the instant claims 30-33, 50-53, and 57-62 are either anticipated by or are an obvious variant of the methods recited in claims 35, 36, 41, 42, 47, 50-58, 67, 69-82, 85-88, 91-102, 106, and 107 of the '707 application.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned US Application Serial No. 11/929,707, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Conclusion

24. No claims are currently allowable. It is noted that the claims are free of the art, but they have been rejected for other reasons, specifically, obviousness-type double patenting.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANGELA BERTAGNA whose telephone number is (571)272-8291. The examiner can normally be reached on M-F, 9- 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/GARY BENZION/
Supervisory Patent Examiner, Art Unit 1637